**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| MARY MADISON, | ) | |
| | ) | |
| Plaintiff, | ) | No. 23-cv-16476 |
| v. | ) | |
| | ) | Hon. Manish S. Shah |
| CREATIVE WERKS LLC, | ) | |
| and STEVE SCHROEDER, Individually | ) | |
| | ) | |
| Defendants. | ) | |

**DEFENDANTS' REPLY TO PLAINTIFF'S RESPONSE TO RULE 56.1 STATEMENT OF UNDISPUTED FACTS AND STATEMENT OF ADDITIONAL MATERIAL FACTS**

Defendants, Creative Werks, LLC and Steven Schroeder, set forth as follows in Reply to Plaintiff's Response to Rule 56.1 Statement of Undisputed Facts and Statement of Additional Material Facts.

**1.** Denied. Defendants denied this in their Answer. (Answer ¶11(b), Dkt. #53.)

**Reply to Response**: While Plaintiff denies paragraph 1 of Defendant's Rule 56.1 Statement of Undisputed Material Facts, her reference to the Answer does not address, relate or refute the assertions of fact.

**2.** Admitted.

**Reply to Response:** None

**3.** Denied in part. The FDA inspection report outlines the responsibilities of individuals engaged in regulatory operations. Defendants have admitted that Mr. Zicher was involved in compliance-related functions (Answer ¶7, Dkt. #53) and that Plaintiff was hired for her regulatory and quality expertise (Answer ¶8, Dkt. #53). Although Zicher held a PCQI certification, such certification is not mandatory under the Food Safety Modernization Act (FSMA); compliance is determined by the adequacy of the Food Safety Plan, not by individual credentials. See 21 C.F.R. § 117.180(c)(1).

**Reply to Response**: While Plaintiff purported "Denied in part" the allegations of fact, she cites to no contrary factual averments with respect to paragraph 3.

**4.** Admitted.

**Reply to Response**: None.

**5.** Admitted.

**Reply to Response**: None

**6.** Admitted in part. The FDA informed Defendants that they were coming. The reason for the visit stemmed from a consumer complaint (170623), Plaintiff's compl. Dkt # 1 & Dkt. # 81-1 Exhibit 2 pg. 59#1) Zicher confirms that the initial visit was focused on the consumer complaint (Def. Exhibit 3, pg 75 Dkt. #81), encompassing the issue cited in Zicher's email. Defendants' facility had not been registered and hence necessitating a routine inspection. The FDA report (Def. Exhibit 2-Dkt. #81) indicates that this was the Defendants' first inspection (pg. 58) since the enactment of FSMA in 2011. Defendants admit that they have been in business since 1999 (Dkt #81-¶11 pg 4)

**Reply to Response**: While Plaintiff sets forth additional facts, her assertion regarding the FDA inspection at issue being the "first" is not supported by the record. Rather, what Plaintiff refers to in the FDA audit is merely a statement that the particular facility of Creative Werks was the subject of its first FDA audit, but it does not reflect that Creative Werks had not received FDA inspections at other Creative Werk facility addresses.

**7.** Denied in part. The FDA consumer complaint indicates that Pepsi contacted Defendants about the adulterated Cheeto product as a direct result of a consumer complaint. (Dkt. #1-consumer complaint; See also Def. Ex 2 pg. 58) It is admitted by Defendants that there was a prior similar customer complaint, evidencing repeated introduction of adulterated product into the stream of commerce in violation of the FFDCA.

**Reply to Response**: Objection to the extent the last sentence asserts an admission of an "adulterated" product or violating FFDCA, with no citation to the record by Plaintiff. Defendants further dispute that the FDA audit inspector report indicates that "Pepsi contacted Defendants about the adulterated Cheeto product as a direct result of a consumer complaint."

Plaintiff refers to Def. Ex. 2, pg. 58 of the Rule 56.1 Statement in support, however that is not reflected anywhere therein. To the extent Plaintiff bases the same allegation upon language appearing in as Exhibit 10 to her Complaint, Defendants object to utilizing same as a proper citation of record as it constituted in-admissible hearsay and Plaintiff has not established a foundation or exception for proffering of same.

**8.** Denied in part, the FDA report states that the consumer became ill after eating the Cheeto product and asserted that black mold was present. (Dkt. #81-Exhibit 2 pg 59)

**Reply to Response**: While Plaintiff appears to deny in part, she does not dispute any of the allegations in paragraph 8.

**9.** Admitted in part that the product was no longer packaged at Creative Werks during Plaintiff's tenure. Plaintiff cannot either confirm or deny the remaining assertions.

**Reply to Response**: None.

**10.** Denied in part. While Defendants reference a third-party audit, it was not conducted under FDA authority and does not establish FSMA compliance. Third-party audits are voluntary and Plaintiff disputes that the audit validated systemic compliance with FSMA. (Madison Declaration-; Defendants Ex. 6 Nestlé Audit-Dkt 81; FDA Report- Exhibit 2-Dkt 81.) Further, Plaintiff contests its sufficiency under applicable federal standards. Additionally, the FDA noted in Def. Exhibit 2 Dkt. 81 that this was Defendants' first inspection pg. 58. Further, the FDA inspector indicated that due to the facility not being registered as required, the facility had not been inspected. Every customer of the Defendants that manufactures, handles, or packs food products or food-related products is regulated by the FDA.

**Reply to Response**: If and to the extent Plaintiff sought to assert additional facts, Defendants object to the extent there are several allegations without any citation to the record. Defendants further object to the extent argument is made by Plaintiff as to import of the allegations, not disputing substance of same.

**11.** Denied in part. Although Defendants reference audit records, Plaintiff contests their relevance under FSMA. These records do not resolve the hazard analysis and preventive controls deficiencies or the various other subparts of 21 CFR 117 identified in Plaintiff's Risk Analysis. (See Ex. 2; FDA Report- DKt 81; and in the SQF report (Def. Exhibit 5-Dkt. #81) and Nestle audit (Def. Exhibit 6 Dkt. #81 pg 3) that further references 31 non-conformances (13 Major and 18 Minor). Although the audit records may exist, they do not address the systemic concerns raised by Plaintiff, nor do they provide FSMA validation or include corrective actions required by law.

**Reply to Response:** While Plaintiff purportedly "Denied in part", the allegations, she does not set forth any assertions of fact that dispute the particular allegations in paragraph 11.

**12.** Denied in part. Plaintiff acknowledges the audit date but contests the scope and effectiveness of the review. Defendants failed to address FDA-reported violations and internal inconsistencies with Zicher's Food Safety Plan. (Dkt. 81 & Plaintiff's Undisputed Facts Stmt. ¶14, ¶49–50.) Plaintiff acknowledges the audit date but disputes the completeness and conclusions drawn by Defendants, given the concerns noted in the FDA report (Def. Exhibit 2 pg. 58), subsequent compliance failures and unresolved safety risks.

**Reply to Response**: While Plaintiff purportedly "Denied in part", the allegations, she does not set forth any assertions of fact that dispute the particular allegations in paragraph 12. To the extent Plaintiff seeks to assert additional facts, the citation to the record does not support her assertions regarding Defendant's response to any FDA inspection or purported food safety plan issues.

**13.** Denied in part. The existence of audits is not disputed, but Plaintiff denies they reflect adequate FSMA compliance. The audit omitted material risk factors that were documented in Plaintiff's Risk Analysis and third-party observations. (See Def. Ex. 2 & 6-Dkt #81.) Further, the FDA report states that a comprehensive audit was not conducted (Def. Exhibit 2 pg. 67) Plaintiff does not contest the occurrence of audits but denies that they demonstrate compliance with

FSMA requirements or correct the violations she documented.

**Reply to Response**: None.

**14.** Denied in part. Plaintiff challenges the reliability of audit conclusions due to known recurring violations. These audits were not comprehensive and failed to reflect systemic non-compliance patterns noted by Plaintiff and corroborated by the FDA. (FDA Report; Def. Ex. 2; Pl.'s Undisputed Stmt. ¶49–52.) Plaintiff disputes Defendants' interpretation of "NAI" as it was clearly noted in the FDA report that five (5) concerns/observations were made and that Zicher promised to correct these non-conformances (Def. Exhibit 2 pg. 58). Additionally, as stated, the FDA admits that it did not conduct a full-on audit. (DKT #81-Exhibit 2 pg. 67). The FDA audit was not a reliable indicator of FSMA compliance due to repeated consumer complaints (DKT #1-consumer complaint exhibits), infractions—Nestle audit (Def. Exhibit 6-Defendants' Exhibit\ is not representative of the outstanding non-conformances during the relevant time of Plaintiff's employment. The document as represented has all of the outstanding issues closed and that was not the case during the relevant time. See Plaintiff's declaration, Exhibit 10 and lack of proper documentation supporting compliance controls (Def. Exhibit 6-Dkt #81)

**Reply to Response:** While Plaintiff purportedly "Denied in part", these allegations, she does not set forth any assertions of fact that dispute the particular allegations in paragraph 14.

**15.** Denied in part. 483 notices are issued or not issued at the discretion of the FDA inspector. There were five (5) observations made and noted by the FDA inspector with the understanding that these issues would be remediated. (Def. Exhibit 2- pg 58 Dkt. #81) Third-party audits, including the Nestlé audit, were voluntary and not substitutes for regulatory compliance. Plaintiff's Risk Analysis identified uncorrected FSMA violations which Defendants failed to address, despite internal acknowledgment. (Answer ¶8, Dkt. #53; Ex. 2.) The third-party audits cited by Defendants were voluntary and not conducted under FDA protocols. Plaintiff's Risk Analysis identified key regulatory violations not reflected in those audits.

**Reply to Response:** While Plaintiff purportedly "Denied in part", with respect to the

allegations, she does not set forth any assertions of fact that dispute the particular allegations in paragraph 15. Defendants object to the second sentence as consisting of argument and with no citation to the record.

**16.** Admitted in part. Defendants' omitted Plaintiff's attachment relative to the email that was sent. Further, these emails went to Schroeder, LeMay and Sammath, among other salaried employees of Creative Werks as evidenced by the emails. Pointedly, Zicher sent two (2) emails, one on September 28 and another on September 29, 2022, discussing the Cheeto investigation in both emails and renumerating the five (5) observations noted by the FDA inspector on September 29, 2022 (Def. Exhibits 2 & 3 Dkt. #81).

**Reply to Response**: None.

**17.** Denied in part. The cited audit fails to address the same operational and regulatory deficiencies identified by Plaintiff. Independent review and expert testimony corroborate Plaintiff's findings (Madison Declaration-Exhibit 27 (Dr. Hutt report). Plaintiff disputes the interpretation of the audit's conclusions, as Defendants failed to acknowledge deficiencies documented in Plaintiff's Risk Analysis, FDA inspection reports, third-party SQF audits, and customer audits. Moreover, Plaintiff lacks knowledge of any events occurring after her suspension and exclusion from Defendants' facility in 2023 and therefore cannot admit to any assertions based on post-suspension conduct.

**Reply to Response:** Plaintiff's Response does not cite anything to dispute the allegations regarding the number of third party or FDA audits asserted by Defendants. Other than the third sentence of the Response, there are no citation to the record. Plaintiff's citation to her Declaration, does not dispute the allegations made by Defendant.

**18.** Denied in part. Third-party audits may be required by customers, but are not a requisites of the FDA under FSMA. Plaintiff denies that the audit scope included preventive controls, allergen management, change management and other hazard identification metrics as required under FSMA (Def. Exhibit 6 Dkt. #81). Defendants fail to show that such items were properly

audited. Plaintiff challenges the characterization of the audit scope and its sufficiency to validate systemic food safety risks identified under her role.

**Reply to Response**: Notwithstanding the "denial in part" set forth by Plaintiff, nothing in her response disputes the allegations of Defendants. If and to the extent asserted as additional facts, Defendants deny the legal conclusions asserted by Plaintiff, and the citation of record by Plaintiff does not otherwise establish same.

**19.** Denied in part. Plaintiff identified documented gaps in record keeping, sanitation, traceability etc…that were not captured in Defendants' audit, considering that the standards are not the same. These were confirmed in third-party and Nestlé audit reviews. (Ex. 6-Dket # 81) While audit outcomes are acknowledged, Plaintiff denies they reflect lawful compliance due to substantive and repeated control gaps she documented. Further, Plaintiff denies reviewing the March 29, 2023, SQF audit. Further, admitting a rating on a voluntary audit does not equate to regulatory compliance.

**Reply to Response:** Notwithstanding the "denial in part" set forth by Plaintiff, nothing in her response disputes the allegations of Defendant. Defendants further note that the citation of record cited by Plaintiff with regard to the third-party and Nestle audits do not support the assertion of fact set forth by Plaintiff.

**20.** Denied in part. Plaintiff's Risk Analysis relied on federal standards under FSMA and was corroborated by internal email communications and audit failings. The audits cited by Defendants do not rebut or nullify those findings. (Dkt #53 and 81) Plaintiff disputes that the audits negate or supersede her Risk Analysis, which was based on FSMA statutory requirements and professional judgment as a regulatory professional. Further, Defendants referenced Exhibit 6 (Dkt #81) identifies 31 non-conformances, 13 which are major findings and 18 minor findings.

Further, by Defendants' own admission these customers are regulated by the FDA and in turn require that its agents comply with these same guidelines.

**Reply to Responses:** Notwithstanding the "denial in part" set forth by Plaintiff, nothing in her response disputes the allegations of Defendants. If and to the extent Plaintiff intended her response to be considered additional facts: her assertion that her Risk Analysis "relied on federal standards under FSMA and was corroborated by internal email communications and audit failings" is not supported by any citation to the record. Plaintiffs remaining statements concerning the audits are argumentative, conclusory and the reported citations of record do not facially support Plaintiff's assertions of undisputed facts.

**21.** Denied in part. The record shows repeated compliance failures and systemic gaps that were not resolved through third-party audit activity. Defendants' own expert and Zicher disagreed on the adequacy of the compliance program. (Declaration of Zicher to the Department of Labour and Declaration of Knuntson 2023) Creative Werks underwent third-party audits, which are voluntary and do not equate to FSMA compliance. The audits identified systemic and repeated compliance failures. (Def. Ex. 2 Dkt #81)

**Reply to Responses:** Notwithstanding the "denial in part" set forth by Plaintiff, nothing in her response disputes the specific allegations of Defendants. If and to the extent Plaintiff intended her response to be considered additional facts, Plaintiff does not adequately cite to any portion of the record to adequately support the assertions of facts made by Plaintiff.

**22.** Admitted in part. To the extent that was the directive given by Zicher; however, this was not the correct standard as Food Safety Plans are requisite of FSMA. Just as the FDA inspector stated that Zicher's work product was hard to read and understand and had errors ( Def. Exhibit 2 Dkt #81 pg 71), Plaintiff had that same experience as the FDA inspector with the food safety plan being hard to read and understand and filled with errors that Zicher had provided to her.

**Reply to Response:** While Plaintiff asserts "admitted in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. If and to the extent she intended her response to be additional facts, she similarly does not cite to portions of the record establishing them as undisputed.

**23.** Admitted in part. Plaintiff objects to Defendants referring to the risk analysis as a legal analysis. That is a mischaracterization of the document presented to Schroeder on October 21, 2022. Further, the referenced exhibits to the Risk Analysis were omitted.

**Reply to Response:** While Plaintiff asserts "admitted in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. Plaintiff's argument of "mischaracterization" is not explained or supported by any citation to the record.

**24.** Denied in part. While Defendants claim an open-door policy, LeMay did not follow through with meeting Plaintiff. (Answer ¶19, 55-57 & fn. 88 Dkt. #53.)

**Reply to Response**: While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants.

**25.** Denied in part. To the extent that the Risk Analysis was shared with the individuals, as stated by Defendants, the only individual who arguably has the requisite knowledge to derive the conclusion proffered is Zicher and to which any statements made by Zicher are self-serving.

Plaintiff is not aware of whom the Risk Analysis was subsequently shared with, as Plaintiff was excluded from any internal investigations. (Dkt #53 ¶75)

**Reply to Response**: While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. To the extent intended as additional facts, they consist of arguments as to the import of the facts asserted by Defendant only.

**26.** Denied in part. FDA and Nestlé audit reports confirmed issues similar to those raised by Plaintiff, including that documents prepared by Zicher were hard to understand and inaccurate. (Def. Ex. 2, pg. 71 and Ex. 6) Plaintiff addressed these various issues with Zicher over the course of time and attempted to address issues through HR (Dkt #81 ¶24). Defendants' open-door policy is acknowledged in their Answer. (Answer ¶19, 55-57 & fn. 88 Dkt. #53.) The FDA report confirmed that the food safety documents created under Zicher's leadership were confusing and error-prone. (Ex. 2; Ex. 2, pg. 71) The Nestlé audit report demonstrated repeated deficiencies and non-conformances (Def. Exhibit 6 Dkt. #81) and further admitted by Defendants ¶20 Dkt #81.

**Reply to Response:** While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. To the extent intended as additional facts, her statements do not reflect that she actually brought any Risk Analysis issues to anyone in Creative Werks prior to giving them to Steve Schroeder, nor does the FDA cited to by Plaintiff refer to Mr. Zicher or his leadership or the like. The remaining asserted factual statements of Plaintiff are argumentative and does not cite to portions of the record indicating they are undisputed.

**27.** Denied in part. Plaintiff was never informed that she was being suspended for the unprofessional report. This is in contradiction to Def. Exhibit 10-Dkt.#81 that states the suspension was for the report tendered to Schoreder and the conversation. Plaintiff was excluded

from Defendants' internal investigation despite being central to the compliance concerns. (Dkt. #53 ¶75).

**Reply to Responses.** While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. The citation in the record cited by Defendants indisputably indicates what was communicated to Plaintiff as the reason for her suspension, which she denies but does not explain why or how. To the extent intended as additional facts, there is no citation to the record reflecting the undisputed nature of the assertions made by Plaintiff.

**28.** Denied in part. Defendants retained outside counsel to question Plaintiff after her suspension, not as part of an internal review. (Dkt. #53 ¶75-Pl's. Undisputed facts 62 & 68). Plaintiff was suspended on October 26, 2022, and excluded from the internal investigation(Dkt. #53 ¶75; see also Dkt 81). Defendants asserted to Plaintiff that the outside counsel was an independent fact finder (Dkt. #53 ¶82) She was later interviewed by outside counsel on December 20, 2022, where her counsel was present. The outside counsel later claimed privilege and refused to provide the investigation findings (Dkt. #53 ¶93).

**Reply to Responses**: While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. To the extent intended as additional facts, the citations to the record by Plaintiff do not support them as being undisputed facts. Defendants do not deny that Plaintiff was interviewed by outside counsel before being terminated, nor does it deny, upon information and belief, that said counsel refused to produce work product on the basis of privilege.

**29.** Admitted in part. However, this was not the first time Plaintiff raised issues of disparate treatment—This issue was raised on November 1 and 8, 2022, and again on December 20, 2022, in addition to January 23, 2023. Madison Declaration.

**Reply to Response**: While Plaintiff asserts "denied in part," her response contains no citation of any portion of the record denying any of the facts set forth by Defendants. To the extent intended as additional facts, Defendants specifically deny that Plaintiff ever raised the issue of disparate treatment before being terminated (i.e. not raised by her until January 23, 2023). (See Exhibit 12 to Defendants' Rule 56.1 Statement of Facts and Declaration of LeMay in Support thereof). Plaintiff cites to her Declaration in support for her proposition that she asserted discrimination prior to January 23, 2023, however, there is statement in or exhibit to her Declaration establishing same. At best her Declaration asserts merely that "I communicated to Creative Werks the adverse employment actions, which were taken against me, including but not limited to being retaliated against for identifying and raising non-compliance issues to Mr. Schroeder related to violations of FSMA…I further addressed the issue of not being afforded an opportunity to be a part of any investigation (Exhibit 21)." (See Plaintiff's Declaration, Docket 101, pg. 13-14). Plaintiffs' Declaration does not set forth anything about the timing of such purported reports to the Creative Werks and do not thus overcome the specific sworn statements to the contrary by Defendants.

**30.** Admitted in part. Prior to January 23, 2023 Plaintiff had not filed any legal action against Defendants. However, Plaintiff continued raising regulatory issues after her suspension, beginning in November of 2022, including on December 20, 2022, during the meeting with outside counsel, and again in January 2023. *Ibid*

**Reply to Response:** While Plaintiff states that par. 30 is "Admitted in part" she does not set forth any rebuttal or additional facts disputing Defendant's factual assertion that "Prior to January 23, 2022, Plaintiff never filed any legal actions against Defendant nor did she make

any communications about disparate treatment or discrimination."

**31.** Deny the mischaracterization of the Risk Analysis as Legal Analysis. Admitted in part that Plaintiff did state that inherent compliance failures can create irreparable harms to all stakeholders. Defendants contradict themselves when they state that they have had dozens of regulatory audits, whereas the FDA report states that the September 2022 audit was the Defendants' first audit. (Def. Exhibit 2 page 58). SQF Def. Exhibit 5 and other third-party audits do not comport to FSMA compliance. Additionally, Defendants' statements about Plaintiff's report are sheer conjecture and cannot be substantiated by fact, science or law.

**Reply to Response:** While Plaintiff materially "Admits in part" as to paragraph 31, she cites to no portions of the record disputing any of the factual averments therein. Plaintiff, moreover, misstates the allegations in paragraph 31, which does not state that they had "dozens of regulatory audits." In relevant part, par. 31 asserts that a statement made by Plaintiff "is directly contradicted by dozens of regulatory, SQF and customer audits finding otherwise." Plaintiff's remaining assertions have no citation to the record.

**32.** Denied. Plaintiff possesses a Master's in Regulatory Science from Johns Hopkins, a Chemistry degree, and holds PCQI credentials, and is a certified ISO 9001 and Food Safety Lead Auditor. Plaintiff's education and professional certifications demonstrate expertise consistent with the regulatory assessments she provided. (Dkt.#53 ¶8). There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 32.

**33.** Denied. Defendants and Defendants' customers are regulated by the FDA and are subject to the statutory and regulatory scheme promulgated by Congress. Further Plaintiff did not have to read the agreements between Defendants and its customers, because regulatory and statutory

constructs supersede all other agreements and are the controlling requisites. Plaintiff's role and responsibilities at Creative Werks included, but were not limited to, evaluating FSMA compliance and overseeing Food Safety Plans (Answer ¶8, Dkt. #53).

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 33.

**34.** Denied. Plaintiff's Risk Analysis was grounded in FSMA-mandated practices for hazard identification and preventive controls. Failing to comply with FSMA would inherently result in a breach of contract and fiduciary duty to the customer under FSMA. There is a mischaracterization by Defendants of the Risk Analysis as a Legal Analysis.

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 34. Additionally, Plaintiff's response has no citations to the record.

**35.** Denied in part. There is a mischaracterization of the Risk Analysis as a Legal Analysis. Admitted in part that Defendants have not been compliant with the Preventive Controls regulations. Defendants Exhibit 5 Dkt #81 SQF audit states that Defendants do not have any Preventive Process Controls (PPC's) and identified it as a non-conformity. A food safety plan cannot exist without Preventive Process Controls (PPC's). Nestle's audit also identifies non-conformities relative to Hazard Analysis and Critical Control Points (HACCP) (Defendants Exhibit 6 (Dkt #81), Plaintiff's declaration Exhibit 6 and 10; Dr. Catherine Hutt Exhibit 27). Plaintiff's Risk Analysis applied the statutory and scientific framework expected of FSMA PCQI personnel.

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 35.

**36.** Denied. There is no evidence that Plaintiff's methods were deficient. Instead, Defendants

failed to address her documented concerns. (Dkt.#40, 53 & 81) Further, there was a similar situation with Med-Fast in October of 2022, who raised concerns about several of Defendants' operational practices (Complaint-Dkt. #1) Further, lost business is not limited to current customer retention, but also extends to loss business opportunities rooted in non-compliance or the lack of evidence in complying with prevailing mandates.

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 36.

**37.** Admitted in part, but denied in that there is a mischaracterization of the Risk Analysis as a Legal Analysis. Plaintiff holds relevant degrees and certifications in Business Analytics from Harvard University and based her Risk Analysis on FSMA statutory frameworks. Plaintiff contends under the FDA's traceability rule that Defendants had a legal burden to discharge that it admits that it believes does not exist.(Dkt #81 ¶74)

**Reply to Response:** While purportedly "Admitted in Part" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 37.

**38.** Admitted in part. Plaintiff identified multiple FSMA violations, including insufficient hazard controls and poor documentation practices. (Def. Ex 2 pg 58 and Ex. 6, Dkt #1) This alone would not allow Pepsi or any other company to discharge themselves of their legal burdens under FSMA. Plaintiff's concerns were based on FSMA standards and gaps in food safety procedures.

**Reply to Response:** While purportedly "Admitted in Part" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 38.

**39.** Admit in part and Plaintiff asserts that there is a mischaracterization of the Risk Analysis as a Legal Analysis. Defendants never provided evidence that Plaintiff's findings were scientifically or statutorily invalid or that they conducted an independent scientific or statutory review. (Dkt.#40, 53, & 81). In addition to Plaintiff raising these regulatory issues, the Nestle audit also supports regulatory non-compliance, as well as the FDA report that outlines the regulatory framework. Defendants have no metrics or systems in place to support compliance with the

framework identified in the FDA report.

**Reply to Response:** While purportedly "Admitted in part" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 39. Moreover, portions of Plaintiff's response have no citation to the record.

**40.** Denied. Plaintiff's compliance findings were based on document review and comparison to FSMA requirements-21 CFR 117 and the relevant subparts, not speculation. There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**Reply to Response:** While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 40, which merely recited a portion of Plaintiff's deposition testimony.

**41.** Denied. Plaintiff's use of risk analysis is aligned with FSMA methodology, and her assessments were specific, documented, and tied to statutory obligations. (Def. Ex. 3-Dkt #81) Defendants abandoned their expert witness in favour of Zicher and Schroeder to support regulatory compliance and interpretation (Dkt. #81)

**Reply to Response**: While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 41.

**42.** Denied. There is no record of Plaintiff's recommendations being formally reviewed and rebutted by Defendants or any qualified food safety expert. (Dkt. 40, 53, &81) Further, the FDA report states that the consumer became ill after eating the Cheeto product. Def. Exhibit 2 Dkt. #81 pg 59.

**Reply to Response**: While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 42. Madison admitted to having no knowledge as to whether any customer sought or obtained medical attention relating to any Cheeto compliant. (Madison Dep. 89:17 - 25).

**43.** Denied. Plaintiff's documentation included root cause analysis and hazard mapping. No

contrary analysis has been submitted by Defendants. (Dkt. 40, 53, and 81)

**Reply to Response**: While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 43.

**44.** Denied in part. Plaintiff was only aware of what the FDA inspector stated that the consumer had become ill— Def. Exhibit 2 Dkt. #81 pg 59. The Risk Analysis was developed from an independent review of policies, procedures, and operational documents or the lack thereof, relevant to FSMA and the FDA investigation and audit (Def. Ex 2-Dkt #81). There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**Reply to Response**: While purportedly "Denied in part" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 44.

**45.** Denied. Nestle's audit confirms that Defendants lacked change control (Def. Exhibit 6 ). Further, there was no evidence of change control. Plaintiff conducted her analysis consistent with her regulatory science background and job responsibilities in compliance with FSMA. There is a mischaracterization of the Risk Analysis as a Legal Analysis.

**Reply to Response**: While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 45

**46.** Denied. Defendants failed to identify any scientific or regulatory basis for disputing Plaintiff's findings. The structure, content, and implementation of the cited plans failed to comply with the requirements of 21 C.F.R. Part 117, including the obligation to maintain a complete and site-specific Food Safety Plan for each facility (see 21 C.F.R. § 117.126(a)(1)). Moreover, Defendants did not demonstrate that the number or scope of plans aligned with the

hazard analysis and preventive control mandates applicable to each site. These deficiencies are further supported by the expert findings in the Dr. Catherine Hutt–Madison Declaration (Ex. 27) and (Dkt. #53 ¶¶60-61)

**Reply to Response**: While purportedly "Denied" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 46. If and to the extent Plaintiff sought to submit statements of additional fact, plaintiff make a legal argument concerning 21 C.F.R. § 117.126(a)(1)). Plaintiff further cites to no portion of the record in support of her remaining contentions.

**47.** Denied. Plaintiff's findings were specific, documented, and consistent with regulatory expectations under FSMA. Further, Defendants have not provided any admissible evidence to contradict this assertion. (Dkt.#81)

**Reply to Response:** While purportedly "Denied Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 47.

**48.** Plaintiff cannot address the thoughts and opinions of Defendants, as that is a subjective statement based upon mere conjecture. Further, Zicher raised similar concerns as Plaintiff but was not suspended or disciplined. (Answer ¶¶7, 60-61, 86 &99 Dkt. #53.)

**Reply to Response**: Plaintiff does not dispute the factual assertion made in paragraph 48.

**49.** Denied. Plaintiff did not discuss with Mr. Schroeder whether the Risk Analysis had been shared with Mr. Zicher. However, Defendants' own audit logs reflect repeat nonconformities spanning multiple years under Zicher's oversight (Dkt.#81- Ex 2 & 6), underscoring systemic quality failures. Defendants also claimed to maintain an open-door policy, and Mr. Schroeder admitted to routinely engaging with employees regarding operational issues, including nonconformances (Dkt. #53 ¶55-57 & fn. 88). This practice stands in stark contrast to Defendants' newly asserted claim of a breached 'corporate protocol'—a policy for which they

have produced no written documentation or evidence of existence. The absence of such a policy further undermines the credibility of Defendants' post hoc justification.

**Reply to Response**: While purportedly "Denied" Plaintiff does not dispute the factual assertion made in paragraph 48. To the extent Plaintiff seeks to assert additional facts, she cites to nothing in the records objectively supporting any "systematic quality failures."

**50.** Admitted in part. Nestle also concurred in its audit that Defendants should not rely on the customer. (Defendants Exhibit 6, Plaintiff's declaration Exhibit 10). Internal records show Zicher was involved in food safety planning and contributed to non-compliant documents identified by Plaintiff. i.e food safety plans. FSMA requires that Defendants engage in preventive risk-based analysis–Food Safety Modernization Act. Plaintiff's Risk Analysis addressed systemic issues that were validated by third-party and FDA findings. (Ex. 2; FDA Report, Def. Exhibit 5 and 6).

**Reply to Response**: While purportedly "Admitted in part" Plaintiff does not dispute the factual assertions made in paragraph 50. To the extent Plaintiff seeks to assert any additional facts, Plaintiff does not reflect what in the FDA Report "validated" anything concerning Plaintiff's Risk Analysis in the record as undisputed.

**51.** Admitted in part. Zicher was not responsive to the requests and queries made by the FDA inspector, as evidenced by the FDA inspector, who stated that she requested one document, but was provided another (Def. Exhibit 2 pg. 71) . And that document was hard to read and understand and had errors. Plaintiff asserted that the answers should be responsive to the questions and eliminate extraneous and erroneous information.

**Reply to Response**: While purportedly "Admitted in part" Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 51.

**52.** Denied. No documentation contradicts Plaintiff's FSMA analysis; instead, Defendants removed her without refuting her specific findings (Dkt.#53 ¶¶ 26, 60-61 &75). Further, this contradicts Defendants' Exhibit 3 of Dkt 81 that speaks about and clarifies the regulatory asks.

**Reply to Response**: While purportedly "Denied Plaintiff sets forth no factual assertions contrary to those set forth in paragraph 52.

**53.** Denied. The SQF report (Def. Ex 5) clearly indicates that the X-ray machine is not GRAS and the Food Safety Plan that asserts such was drafted by Zicher. FSMA requires as part of its risk management, a preventive process control—preventive maintenance program. The manufacturers' recommended maintenance may not support the FSMA requirement for the preventive maintenance program and validation requirements. The Risk Analysis was grounded in Plaintiff's scientific training and audit experience and identified unmitigated FSMA risks that Defendants did not dispute (Dkt. # 40, 53 & 81). The Risk Analysis was grounded in Plaintiff's scientific training and audit experience.

**Reply to Response**: None of Plaintiff's purported factual responsive have any citations to the record.

**54.** Admitted.

**Reply to Response**: None.

**55.** Denied. Zicher sent out several emails internally regarding the FDA audit and the five observations ( non-compliances). Further, the email captured the essence of the visit and is corroborated by the FDA report itself. Further, Defendants admit in its answer that Schroeder spoke to Zicher and others about operational issues and non-conformances regularly. Defendants admit that Zicher was not disciplined despite known consumer complaints and quality concerns under his oversight. (DKt. #1-FDA consumer complaints, Def. Ex. 2-pg 58, 59 and 71, Def. Ex 5, Def. Ex 6, Undisputed facts 49-52)

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, the first four (4) sentences of Plaintiff's response and/or additional fact contain no citation to anything in the record. Nothing therein in the last sentence of the Response constitutes a denial of any allegations of fact in paragraph 55.

**56.** Denied. Plaintiff and Zicher engaged in analogous compliance activities, yet Plaintiff alone was suspended. This supports a claim of disparate treatment. (Dkt.#53- ¶60-61)

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 56.

**57.** Denied. The Nestle audit espouses systematic failures, as well as the Wilton/Trace Gains (Dkt #1), and SQF audit contexts. (Defendants Exhibit 6, Madison Declaration Exhibit 10). Further, Defendants acknowledged that there were deficiencies with Nestle (Dkt. # 81 ¶20)

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 57. Plaintiff refers to a third party audit finding in the record, but does not address the assertion that "Zicher" did not report any systematic failure of Creative Werks to comply with FSMA to the Company or Schroeder."

**58.** Denied. When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings and consumer complaints to management, he put them on notice that there was a non-conformity. A nonconformity is a breach of fiduciary duty. (Def. Ex 2 and 6)

**Reply to Response**: Reply to Response: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 58. Additionally, Plaintiff asserts a legal argument as to what constitutes a breach of fiduciary duty, not addressing whether Zicher reported a breach of a fiduciary duty.

**59.** Admitted

**Reply to Response**: None.

**60.** Denied. When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings and consumer complaints to management to management he put them on notice that there was a non-conformity. In particular, the Nestle audit specifically states

that a repeated infraction has occurred. A non-conformity is a violation of the FFDCA. (Def. Ex 2 and 6)

**Reply to Response:** While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 60. While Plaintiff asserts that Zicher reported audit deficiencies, Plaintiff does not cite to any evidence in the record that Zicher reported any audit deficiencies to Defendants, the crux of paragraph 60.

**61.** Denied in part. Zicher stated in his 2023 affidavit to the Department of Labour that the food safety plans were not compliant, in contradiction to the Defendants' expert witness who stated that the food safety plans were compliant. Also see Dr. Catherine Hutt's Expert report- Madison Declaration Exhibit 27.

**Reply to Response**: While Plaintiff purportedly "Denied in part" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 61. Moreover, to the extent Plaintiff seeks to assert an additional fact, the allegations concerning Zicher's purported statement to the Department of Labor was made after Plaintiff was terminated and in response to her DOL complaint, and does not reflect an instance of Zicher engaged in the same conduct as Plaintiff as when she was an employee.

**62.** Denied. Zicher affirmatively communicated to company leadership that their interpretation and application of FSMA mandates—particularly regarding the adequacy of Food Safety Plans and hazard analysis and other issues Plaintiff raised—were sufficient, despite clear regulatory deficiencies (Zicher Aff. ¶42-Dkt #81). These assurances directly contradicted Plaintiff's documented findings and contributed to the company's misinterpretation of its legal obligations under 21 C.F.R. Part 117. Zicher's influence not only undermined Plaintiff's credibility but also steered the organization away from compliance, reinfor*cing the retaliatory context in which Plaintiff's objections were dismissed.*

**Reply to Response:** While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 62. Defendants

statements in paragraph 62 relate to factual averments of Zicher as a comparator when Plaintiff was employed by Creative Werks. In her response, Plaintiff asserts that Zicher's act of providing an Affidavit In Support of Defendant's Motion constitutes a comparable act to Plaintiff.

**63.** Denied. Zicher's repeated assertions that certain FSMA-related tasks—such as maintaining adequate HACCP, Hazard Analysis, Food Safety Plans and prohibiting adulterated food from entering the stream of commerce (Dkt. #1 & Dkt. #53)—were unnecessary, contributed to a systemic misinterpretation of regulatory requirements. This conduct not only undermined Plaintiff's compliance-based assessments but also led Defendants to disregard critical mandates under 21 C.F.R. § 117.126(a)(1), which requires a written and facility-specific Food Safety Plan. The company's reliance on Zicher's guidance, despite Plaintiff's documented objections and expert-supported findings (see Madison Declaration-Ex. 27), evidences a pattern of internal misinformation that materially distorted the organization's understanding of its legal obligations.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 63. Defendants' paragraph 63 asserts merely that Zicher has not "reported to the Company that Creative Werks encouraged a disregard for the law," for comparator purposes. Plaintiff's response is an argument that Zicher's alleged actions otherwise reflected a disregard for the law but fails to deny whether he ever reported same.

**64.** Denied. The Nestle audit espouses systemic failures, as well as the Wilton/Trace Gains, and SQF audit contexts Def. Ex 2, 5 & 6 Dkt. #81 and Dkt #1). When Zicher reported the audit deficiencies of Nestle and the Cheeto Product and other customer audit findings, such as Wilton,

and consumer complaints to management he put them on notice that there were non-conformities that occurred over time. There is a mischaracterization of the Risk Analysis as a Legal Analysis

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 64. While Plaintiff asserts that Zicher otherwise reported something equivalent to the substance of what Plaintiff reported in her Risk Analysis, she cites nothing in the record evidencing that Zicher did so.

**65.** Denied. The issues discussed in the Risk analysis were issues that were well-known and had been discussed with Zicher and by Zicher over the course of time with other internal and external stakeholders.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 65. Plaintiff make an allegations without citation to any evidence in the record.

**66.** Denied. Zicher affirmatively communicated to company leadership that their interpretation and application of FSMA mandates—particularly regarding the adequacy of Food Safety Plans and hazard analysis and other issues Plaintiff raised—were sufficient, despite clear regulatory deficiencies (Zicher Aff. ¶42-Dkt 81). These assurances directly contradicted Plaintiff's documented findings and contributed to the company's misinterpretation of its legal obligations under 21 C.F.R. Part 117. Zicher's influence not only undermined Plaintiff's credibility but also steered the organization away from compliance, reinforcing the retaliatory context in which Plaintiff's objections were dismissed.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 66. While Plaintiff asserts that Zicher otherwise reported something equivalent to the substance of what Plaintiff reported in her Risk Analysis, she cites nothing in the record evidencing that Zicher did so.

**67.** Denied. Zicher told Plaintiff on October 3, 2022, at the Benensivlle facility, while waiting for a potential MedFast, that he and Ron Sammath decided what Schroeder should be told. (Madison Declaration)

**Reply to Response**: : While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 67. Additionally, while Plaintiff asserts that Zicher otherwise reported something equivalent to the substance of what Plaintiff reported in her Risk Analysis, she cites nothing in the record evidencing that Zicher did so.

**68.** Denied. Defendants failed to include Plaintiff in any remediation planning or findings. (Dkt. #53 ¶75)

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 68. Additionally, to the extent Plaintiff sought to assert an additional fact, the citation to the record noted by Plaintiff does not support the statement averred to in Plaintiff's response.

**69.** Denied. Defendants admitted that Schroeder regularly spoke to employees about issues. (DKt 53), if Zicher is the Director of Food Safety, it would be improbable that Schroeder did not speak with him about the vast issues surrounding FSMA compliance, including the SQF audit that Defendants are advancing and referencing in their Motion for Summary Judgment (Exhibit 81).

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 69. Rather, moreover, Plaintiff merely asserts an argument seeking to prove a purported fact, but does not cite to anything in the record in support of her supposition.

**70.** Denied. Zicher raised similar regulatory concerns and introduced adulterated product into the stream of commerce, and was not disciplined, despite at least three consumer complaints under his leadership. Defendants admitted as much. (Def.. Ex 2; Dkt. #1 consumer complaints).

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 70. Plaintiff raises an asserted allegations about Zicher, but she does not assert that she engaged in similar actions and was disciplined for same. Otherwise, Plaintiff cites to nothing in the record connecting Zicher with any purported adulterated product entering the marketplace.

**71.** Denied. Plaintiff does not need to read the contractual agreement to know that Defendants and Nestle and its other customers are regulated by the FDA and subject to its regulatory scheme—Food Drug and Cosmetic Act.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 71. Plaintiff merely argues the purported relevance of the allegations.

**72.** Denied in part. Defendants' Exhibit 6 does not correspond to Plaintiff's Exhibit 10, as attached to Plaintiff's Declaration. The audit issues cited therein are not discretionary recommendations but rather compliance metrics, as indicated by the legend in Defendants' own exhibit. Moreover, Defendants have failed to authenticate Exhibit 6 as a true and correct copy, and Nestlé has not submitted any affidavit or declaration attesting to its accuracy or provenance. The document also materially diverges from Plaintiff's records, including those attached as Exhibit 10 and as exhibits to the Risk Analysis at issue—exhibits that Defendants notably omitted. Plaintiff admits in part, solely to the extent that, following her suspension and exclusion from Defendants' facility, she lacks personal knowledge or a legitimate basis to confirm whether the cited issues were subsequently resolved.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 72. Plaintiff does not deny the testimony she provided in her deposition. Plaintiff entire response is unsupported with any citation to anything in the record.

**73.** Denied to the extent that I was well qualified to perform the duties and tasks that I was hired to perform. Further, Defendants cannot point to any poor work performance by Plaintiff. (DKt #53 ¶92 ) Further, Defendants denied terminating Plaintiff Answer ¶11(b), Dkt. #53.) They removed termination from the Joint Status Report. Under the Illinois Personnel Record Review Act (820 ILCS 40/8), Defendants cannot assert termination or discipline that does not appear in Plaintiff's personnel file. Defendants continue to mischaracterize Plaintiff's Risk Analysis as a Legal Analysis.

**Reply to Response**: While Plaintiff purportedly "Denied" all allegations, nothing in her response constitutes a denial of the allegations asserted in paragraph 73. Plaintiff does not set forth any citations in the record disputing the allegations in paragraph 73. Plaintiff sets forth a non-responsive argument as to the purported meaning behind language in a Joint Status Report (without explanation), and makes an argument that absent a specific writing in her "personnel file" expressly declaring the basis of her termination, then Defendant could not have a purported basis for same.

**74.** Denied. Defendants have not provided any results of the investigation, nor have they provided any objectively verifiable data supported by fact, science or law, as neither LeMay or Schroeder are experts in Food Safety regulations. What is telling is Defendants abandoned their expert witness for LeMay and Schroeder who have no formal training in regulatory science nor even hold a PCQI certification. Defendants' abandonment of their designated expert—whose opinions failed to satisfy the admissibility standards under Rule 702 of the Federal Rules of Evidence—renders their current reliance on self-styled internal "expertise" both procedurally improper and legally suspect. Having failed to meet their burden to present reliable, qualified expert testimony based on sufficient data and sound methodology, Defendants now attempt to recharacterize their own decision-makers as de facto experts to justify their actions. This post hoc maneuver not only circumvents the gatekeeping function of Rule 702 but also underscores the absence of contemporaneous, evidence-based rationale for the adverse actions taken against Plaintiff.

**Reply to Response**: Defendants object to the entire Response as mere argument and not referring to any citations in the record. Defendants also object to the assertion and/or reference to an "abandoned" designated expert, when there has been no designation of any expert in this case.

On behalf of Defendants, Creative Werks, LLC and Steve Schroeder

/s Jon D. Cohen
Jon D. Cohen, attorney

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